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| 10/734,490 | 12/11/2003 | Mark Zdeblek | PRTS-012 | 1638 |
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| Proteus Biomedical, Inc. Bozicevic, Field & Francis LLP 1900 University Avenue, Suite 200 East Palo Alto, CA 94303 | | | EXAMINER NASSER, ROBERT L | |
| | | | ART UNIT 3735 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/734,490

Applicant(s)

ZDEBLICK ET AL.

Examiner

ROBERT L. NASSER

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-50, 52, 58-68, 96, 99-107 and 110-113 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-50, 52, 58-68, 96, 99-107 and 110-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicant's arguments filed 12/31/2008 have been found to be convincing. Accordingly, the finality of the previous action is hereby withdrawn and the new final rejection entered in its place.

Claims 58 and 61 are objected to as being duplicates of each other.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 62 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 62 is rejected in that it is unclear whether the conductor in this claim is the same as the common conductor in claim 48. Applicant should clarify.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 48, 52, 58-62, 99-102, 104, 106, 107, and 110-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundhar 5209238. Sundhar shows a device having an elongate body 19 having a common conductor, i.e. power, which is coupled to at least two sensors, each of which has its own chip that comprises a

microprocessor, which are axially spaced apart along the length of the body 10. The examiner notes that it appears that the chip does not contain the a/d converter. Rather it is separate from, but connected to the chip. The examiner takes official notice that it is well known to provide an a/d converter on the chip. Hence, it would have been obvious to modify Sundhar to incorporate the a/d converter onto the chip, as it is merely the substitution of one equivalent structure for another. Claims 52 and 102 are rejected in that the lead could be implantable. In addition, it is a "cardiac" lead. Claims 58-61 are rejected in that at least one of the effectors is an ultrasonic device, which has both an actuator and a sensor. Claim 62 is rejected in that connecting the sensor involves connecting a lead to a conductor. Claim 99 is rejected in that since there are multiple chips, each must store an address of its associated sensor. Claim 100 is rejected in that the processor receives and processes data from the a/d converter. Claim 101 is rejected in that the processor receives and processes data from a data conductor connected to the sensors. Claims 104, 106, 107 and 110-112 are rejected for the reasons given above.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48, 49, 52, 57-63, 66-68, 96, 99-107 and 110-113 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al 6163716 in view of Swanson et al 5797903. Edwards shows a device including a body including catheter 118, rod 154

and cap 74, a plurality of effectors connected to the body, where each effector includes a spline 76 having sensing and ablation electrodes thereon which are associated identifiable processor in microconnector 92 (see figure 20 and column 9, beginning at line 13). The processor is on a chip. It is the examiner's position that a microprocessor, like that of Edwards is a digital device, and, as such, it would require an a/d converter. Since Edwards has no other a/d converter, it is the examiner's position that it must be located on the chip. Alternatively, the examiner takes official notice that it is well known to include an a/d converter on a single chip processor. Hence, it would have been obvious to modify Edwards to use a single chip processor/converter, as it is merely the substitution of one known equivalent processor for another. In figures 22 and 24, as discussed in column 10, lines 16-24, each effector, i.e. processor, is connected to a common power line, as there is only one power line for the entire circuit. Also, the power lines extend through ferrule 132. Hence, there is a common conductor that connects to the effectors via surface penetration. The splines, however, are not spaced axially along the length of a carrier. The examiner notes that Edwards has an alternative embodiment where, instead of splines, the electrodes are mounted in arrays on a balloon. In addition, Swanson teaches a mapping and ablation device, like that of Edwards where in figure 11, the electrodes are arranged in a bull's eye configuration, for some applications. Hence, it would have been obvious to modify Edwards to use such a configuration, as it is merely the substitution of one known equivalent configuration for another. In this combination, the effectors are spaced axially along the length of the balloon, which is the carrier and each ring would have its own processor,

just as each spline had its own processor. Claims 49 and 52 are rejected in that the term "cardiac pacing" is an intended use limitation and is met if the reference is capable of the use. Here, structurally, a lead is a lead and hence the lead of Edwards is a pacing lead and it can be implanted. Claims 58-61 are rejected in the effectors include an ablation actuator, i.e. it provides electric current and/or heat and also Edwards teaches that the electrodes can be sensing electrodes, which sense electrical potential. Claim 62 is rejected in that there is at least one lead connected to each ring of electrodes. . Claims 63 and 64 are rejected in that there are 3 leads emanating from the effectors, including power and data. The examiner notes that there inherently is a ground lead as well. Claims 66 and 67 are rejected in that Edwards has in figures 22 and 24, as discussed above, 2 leads 122 and 124 which are common to all the effectors. Claim 68 is rejected in that there is an electrical circuit. Claim 96 is rejected in that the catheter is introduced in and through the heart. Claim 99 is rejected in that each chip has address information stored therein, in order to be identified and to identify individual electrodes. Claims 100 and 101 are rejected in that the processor processes data from the a/d converter and from the data conductor. Claim 102 is rejected for the reasons given with respect to claim 49 above. Claims 103 is rejected in that two of the rings have at least 4 electrodes. Claims 104-107, and 110-113 are rejected in that the combination also teaches the method.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 50, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. Claim 50 is rejected in that there are multiple conductors extending outwardly through the body from the effector. However, there is only one lumen in the body. Applicant has not stated that having a separate lumen for each conductor solves a stated problem or is for a particular purpose. Therefore, it is the examiner's position that the number of lumens would have been a mere matter of design choice for one skilled in the art. Claim 65 is rejected in that at least a portion of the leads are encapsulated by solder.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Whayne et al 6115626 teaches in column 7, lines 39-47, the equivalence of a basket structure and others, such as the one in Swanson above.

Applicant's arguments filed 12/31/2008 have been fully considered but they are moot in view of the new grounds of rejection.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
Art Unit 3735

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April 29, 2009